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January 8, 2010

Tim Orozco, Operations Supervisor
Hazardous Materials Management, and

Mr. Bert Luistro, Program Manager
Office of Environmental Health & Safety

University of California, San Francisco
50 Medical Center Way, Box 0942
San Francisco, CA 94117

SUBJECT: Pharmaceutical Waste Disposal Review (Controlled Substances, In-patient)

Dear Mr. Orozco and Mr. Luistro:

Here is the technical and regulatory review you requested from our Senior Chemist. Please feel free to contact Dr. Gregson or myself should you have any additional questions or require further explanation or assistance.

Sincerely,

Bruce F. Seale, Acting Manager
Pretreatment Program
S.F. PUC, Wastewater Enterprise

Attachment

Tue E 9:30

J Gregson @ SFwater.org

to: Bruce F. Seale, Acting Manager
SFPUC WWE Pretreatment Program
(San Francisco, CA POTW Control Authority)

from: John Gregson, Ph.D., Senior Chemist
SFPUC WWE Pretreatment Program

subject: **Pharmaceutical Waste Disposal Review (Controlled Substances, In-patient)**

date: January 5, 2010

On December 9, 2009 I received from Mr. Lamberto Luistro (UCSF Environmental Health & Safety Office) a list of controlled substances: aqueous solutions of DEA-regulated drugs used in hospital in-patient settings (primarily intravenous administration, I.V.), the unused portions of which are proposed for discharge to the San Francisco sanitary sewer system.

There are currently no compound-specific regulations on this matter. Furthermore, there is general agreement that the residues are non-hazardous, as defined in 22 CCR 66261. California's Medical Waste Management Act does not specifically prohibit the disposal to sewer of small amounts of aqueous pharmaceuticals.

The San Francisco Sewer Use Ordinance (SUO) contains general prohibitions against toxic, hazardous, noxious, or malodorous substances (§123(e)(4)) and bioaccumulative toxic substances in concentrations exceeding the STLC (§123(e)(5)). But specific compounds (such as those in I.V. drug solutions) are not mentioned.

In view of the absence of specific regulations, Mr. Luistro requested guidance from us as to the risk of interference or pass-through at the sewage treatment plants (POTW), or contamination of municipal biosolids—hence, the disposability of such residues.

The list of aqueous solutions is shown in Table 1, along with the typical container volume and concentration of each.

Precise volumes for unused I.V. solutions cannot be predicted with certainty. However, a recent survey of patient care managers at the UCSF Medical Center gave a rough estimate of 4 – 5 L per week of all the aforementioned controlled substances combined, with 1% propofol comprising 30 – 50% of the total (Tim Orozco, UCSF; personal communication, 12/14/09).

Some of the compounds in Table 1 are listed several times, both alone and in combination with other drugs. A total of 23 individual compounds were found in the 33 aqueous solutions comprising Table 1. Grouping these together and using the maximum value when volume ranges are shown, it is possible to compute the total mass of each controlled substance potentially discharged to the sewer system.

With no other basis on which to calculate pollutant mass loadings, I used the rough estimate of Mr. Tim Orozco (above), setting the total volume = 5 L per week, with the

fraction of propofol being 40% (2 L). For the other I.V. solutions, I used the assumption that one "unit" (ampule, bottle, etc.) of each was discharged to the sewer system over the same time period.

From that, the total potential discharge was calculated. No correction was made for counter-ion mass or adjuvant (e.g., liposome). As noted previously, when volume was expressed as a range, the maximum was used to calculate the potential mass loading for that substance.

The results, arranged in decreasing order of potential mass loading, are shown in Table 2.

The chemical structures were then examined and a determination made as to their likely degradability under conditions of pure oxygen, activated sludge digestion, or simple hydrolysis. Comparisons were also made with regard to the compounds' existing presence and concentration in domestic sewage, vs. the total mass to be discharged. The potential risks of drug abuse vs. persistence or pass-through were weighed. These factors were assigned as footnotes to the list of drugs, as shown in Table 2.

The compounds denoted "d", "u", or "m" would be permitted for sewage disposal under most conditions. The compounds denoted "a" or "v" should ordinarily not be discharged to the sewer, but other more serious risks may outweigh this. Lack of benefit would also argue for refraining from sewer disposal, if possible.

Lastly, compounds denoted "p" or "b" are already known or suspected to resist degradation in the sewage plant or the environment. Such compounds must not be discharged to the sewer system. After completing the analysis, none of the compounds in the list were found to be in this category.

TABLE 1

List of Pharmaceutical Solutions Provided by L. Luistro, UCSF (Dec. 9, 2009)

Drug	Volume	Concentration
Acetaminophen w/ Codeine	473 ML	2.4 and 24 mg/mL respectively
Alfentanil	5 mL	500MCG/ML (MCG = micrograms)
Butorphanol Tartrate	2.5 ML	10MG/ML
Cocaine HCl	4 ML	4%
Diazepam	2- 10 mL	5MG/ML
Diphenoxylate w/ Atropine	60 ML	0.5 and 0.005 mg/mL respectively
Fentanyl Citrate	2-50 mL	0.05MG/ML
Guaifenesin-Codeine	5-10 mL	20 and 2 MG/ML respectively
Hydrocodone-Acetaminophen	15 mL	0.5 and 37.4 MG/ML respectively
Hydromorphone HCl	473 ML	1MG/ML
Hydromorphone HCl	1-50 ML	10MG/ML
Ketamine HCl	5 mL	100MG/ML
Lorazepam	1-30 ML	2MG/ML
Meperidine HCl	1 ML	25-100MG/ML
Meperidine HCl	1 mL	50MG/ML
Meperidine HCl	500 ML	1-5 mg/mL
Methadone HCl	30 ML	10MG/ML
Midazolam HCl	2-5 mL	1MG/ML
Midazolam HCl	2-10 mL	5MG/ML
Midazolam HCl	118 ML	2MG/ML
Morphine Sulfate	10 mL	0.5MG/ML
Morphine Sulfate	1-20 mL	15MG/ML
Morphine Sulfate	1 mL	15MG/ML
Morphine Sulfate	30 ML	20MG/ML
Morphine Sulfate Liposome	1.5 mL	10MG/ML
Oxycodone HCl	30 ML	20MG/ML
Oxycodone HCl	5 mL	1 MG/ML
Pentobarbital Sodium	20-50 ML	50MG/ML
Phenobarbital	5-473 mL	4 MG/ML
Phenobarbital Sodium	1 mL	130MG/ML
Phenobarbital Sodium	1ML	65-130MG/ML
Propofol	50 mL	10 mg/mL
Sufentanil Citrate	2-5 mL	50MCG/ML

TABLE 2

	total mg (est. per week)	mg/d (est.)	OK to discharge to sewer without further consideration ?*	footnotes (see below)	discharge subject to caution or restrictions**
propofol	20,000	2,857		a	
codeine	11,372	1,625		d,a,v	
meperidine	2650	379	yes	d,a	
pentobarbital	2500	357		a	
phenobarbital	2022	289	yes	u	
acetaminophen	1696	242		a	
cocaine	1600	229		m,a	
hydromorphone	973	139		m,a	
morphine	935	134		m,a	
oxycodone	605	86		d,m,a	
ketamine	500	71	yes	d,m	
methadone	300	43		m,a	
midazolam	291	42	yes	d,m	
guiafenesin	200	29	yes	u,m	
lorazepam	60	9	yes	d,m	
diazepam	50	7	yes	d,u,m	
diphenoxylate	30	4	yes	d,u,m	
butorphanol	25	4	yes	m	
hydrocodone	8	1	yes	m,a	
alfentanil	3	0.36	yes	d,m	
fentanyl	3	0.36	yes	d,m,a	
atropine	0.30	0.04	yes	d,m	
sufentanil	0.25	0.04	yes	d,m	
acetaminophen			d = readily degraded		
codeine					
hydromorphone			u = already ubiquitous; sequestering yields infinitesimal benefit		
meperidine					
meperidine			m = mass insignificant (e.g., < 1 g per day; 3-5 ug/L at POTW if sequestered & not degraded)		
midazolam					
midazolam			a = possible persistence outweighed by abuse potential		
morphine					
morphine			v = volume insignificant (minimal benefit of sewer disposal, 2 mL)		
morphine					
morphine			p = persistent or risk of persistence		
oxycodone					
phenobarbital			b = bioaccumulative or toxic substance		
phenobarbital					

** d, u, m = OK to discharge to sewer; p, b = do not discharge to sewer; a, v = discharge to sewer permissible but not recommended.

TABLE 2 -- raw data

	Drug	Volume	Concentration	mL	% vol	mg/mL	mg
1	**Propofol**	**50 mL**	**10 mg/mL**	2000	39.70%	10	20000
2	(Acetaminophen w/) **Codeine**			473	9.39%	24	11352
3	Meperidine HCl	1 ML	25-100MG/ML	1	0.02%	100	100
4	Pentobarbital Sodium	20-50 ML	50MG/ML	50	0.99%	50	2500
5	Phenobarbital	5-473 mL	4 MG/ML	473	9.39%	4	1892
6	Hydrocodone-**Acetaminophen**			15	0.30%	37.4	561
7	Cocaine HCl	4 ML	4%	4	0.08%	400	1600
8	Hydromorphone HCl	473 ML	1MG/ML	473	9.39%	1	473
9	Morphine Sulfate	10 mL	0.5MG/ML	10	0.20%	0.5	5
10	Oxycodone HCl	30 ML	20MG/ML	30	0.60%	20	600
11	Ketamine HCl	5 mL	100MG/ML	5	0.10%	100	500
12	Methadone HCl	30 ML	10MG/ML	30	0.60%	10	300
13	Midazolam HCl	2-5 mL	1MG/ML	5	0.10%	1	5
14	**Guaifenesin**-Codeine	5-10 mL	20 and 2 MG/ML respectively	10	0.20%	20	200
15	Lorazepam	1-30 ML	2MG/ML	30	0.60%	2	60
16	Diazepam	2- 10 mL	5MG/ML	10	0.20%	5	50
17	**Diphenoxylate** (w/ Atropine)	60 ML	0.5 and 0.005 mg/mL respectively	60	1.19%	0.5	30
18	Butorphanol Tartrate	2.5 ML	10MG/ML	2.5	0.05%	10	25
19	**Hydrocodone**-Acetaminophen	15 mL	0.5 and 37.4 MG/ML respectively	15	0.30%	0.5	8
20	Alfentanil	5 mL	500MCG/ML (MCG = micrograms)	5	0.10%	0.5	3
21	Fentanyl Citrate	2-50 mL	0.05MG/ML	50	0.99%	0.05	3
22	(Diphenoxylate w/) **Atropine**			60	1.19%	0.005	0.30
23	Sufentanil Citrate	2-5 mL	50MCG/ML	5	0.10%	0.05	0.25
24	**Acetaminophen** (w/ Codeine)	473 ML	2.4 and 24 mg/mL respectively	473	9.39%	2.4	1135
25	Guaifenesin-**Codeine**			10	0.20%	2	20
26	Hydromorphone HCl	1-50 ML	10MG/ML	50	0.99%	10	500
27	Meperidine HCl	1 mL	50MG/ML	1	0.02%	50	50
28	Meperidine HCl	500 ML	1-5 mg/mL	500	9.92%	5	2500
29	Midazolam HCl	2-10 mL	5MG/ML	10	0.20%	5	50
30	Midazolam HCl	118 ML	2MG/ML	118	2.34%	2	236
31	Morphine Sulfate	1-20 mL	15MG/ML	20	0.40%	15	300
32	Morphine Sulfate	1 mL	15MG/ML	1	0.02%	15	15
33	Morphine Sulfate	30 ML	20MG/ML	30	0.60%	20	600
34	Morphine Sulfate Liposome	1.5 mL	10MG/ML	1.5	0.03%	10	15
35	Oxycodone HCl	5 mL	1 MG/ML	5	0.10%	1	5
36	Phenobarbital Sodium	1 mL	130MG/ML	1	0.02%	130	130
37	Phenobarbital Sodium	1ML	65-130MG/ML	1	0.02%	130	130
	* discharge to sanitary sewer in the volume and concentrations listed in this table, per ??			5038	100.00%		

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a = possible persistence outweighed by abuse potential Opioids

v = volume insignificant (minimal benefit of sewer disposal, 2 mL)

p = persistent or risk of persistence found anyway

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